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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,868	07/17/2000	Thomas J. Shaw	75329 77432	8293

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/617,868

Applicant(s)

SHAW, THOMAS J.

Examiner

Kevin C. Simons

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-34, 36-42, 44-50, 52-94 and 96 is/are pending in the application.
- 4a) Of the above claim(s) 35, 43, 51 and 95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-34, 36-50, 52-58, 60-71, 73, 75, 77-94 and 96 is/are rejected.
- 7) ☒ Claim(s) 59, 72, 74 and 76 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claim 95 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 95 is directed to a needle retraction mechanism for a syringe, which is clearly drawn to the subcombination.

Since applicant has received an action for the originally presented claims, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 95 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Drawings***

The drawings are objected to because it appears that 64 and 66 are pointing at the same part. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

As to the drawings specifically (claims 29, 44 and 54), it is unclear what reference numeral represents a continuous retaining member.

As to the drawings specifically (claims 30, 39 and 47), it is unclear what reference numeral represents a structure mounted in the front-end portion of the barrel.

As to the drawings specifically (claims 31, 41 and 49), it is unclear what reference numeral represents a part which protrudes to contact the continuous retaining member.

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As to the drawings specifically (claims 34 and 42), it is unclear what reference numeral represents a means of force applied by said part.

As to the drawings specifically (claims 38 and 46), it is unclear what reference numeral represents the separable part.

As to the drawings specifically (claim 54), it is unclear what reference numeral represents a rigid plunger seal element stop surface.

As to the drawings specifically (claim 56), it is unclear what reference numeral represents the supporting surface.

As to the drawings specifically (claim 60), it is unclear what reference numeral represents the annular shoulder.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: A **continuous** retaining member. What is its reference numeral? Is it the same or different from the retaining member in the specification?

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 29-34, 36-42, 44-50, 52, 54-56 and 81-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 29, 37, 44 and 54, it is unclear what a continuous retaining member means. Note: applicant should clearly define continuous retaining member. Is the retaining member (22) the needle holder?

As to claims 30, 39 and 47, it is unclear what applicant regards as a structure mounted in the front-end portion of the barrel.

As to claims 31, 41 and 49, it is unclear what applicant regards as a part which protrudes to contact the continuous retaining member.

As to claims 34 and 42, it is unclear what applicant regards as a means of force applied by said part.

Claims 38 and 46 recite the limitation "the separable part". There is insufficient antecedent basis for this limitation in the claim. Furthermore, it is unclear what applicant regards as the separable part.

As to claim 54, it is unclear what applicant regards as a rigid plunger seal element stop surface.

As to claim 56, it is unclear what applicant regards as a supporting surface.

As to claim 60, it is unclear what applicant regards as an annular shoulder.

As to claim 81, it is unclear what applicant regards as the retainer member, since it appears that the retainer member does not hold the spring in compression.

As to claim 94, it is unclear what applicant regards as an element.

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**Note:** The claims are replete with vague and indefinite language. Upon correction of the 112 rejections, the claims may be rejected under 102, 103 or other 112 rejections and the case made final. The claims will be examined as best understood!

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 29, 31-34, 36-38, 40-42, 44-46, 48-49, 52, 54-71, 73, 75, 77-81, 83, 85-88, 90-93 and 96 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw U.S. Pat. No. 5,385,551.

Shaw discloses a syringe assembly having a retractable needle and designed for one-time use comprising: a hollow syringe body (10) comprising a barrel (12) having a front end portion (14) containing a retraction mechanism (96) having a retractable needle (34) and a continuous retaining member (102), note: Shaw's device can perform the function of the retaining member, and a back end portion having an opening (figs. 1-4);

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the continuous retaining member having one outside mating surface making a seal (figs. 1, 2 and 5); a plunger (24) having a front end portion comprising a head (42), a supporting surface (44) on the plunger front end portion having a plunger seal element (46) fixed on the supporting surface, and a back end portion with an end cap (56); the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel (figs. 1-4); note: the device of Shaw is capable of performing the function of the retractable needle retraction mechanism; the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction (figs 1-4); as to claims 31, 41 and 49 (figs. 1-4), as to claim 32, (102); as to claims 33-34, 36, 42, 44 and 52 (figs. 1-4); as to claim 37, (see above rejection); as to claims 38 and 46, (102); as to claims 40 and 48, (figs. 1-5); as to claim 45, (see above rejection); as to claim 52, (figs. 1-5); as to claim 54, (see above rejection); as to claim 55, (figs. 1-5); as to claim 56, (see above rejection); as to claim 57, (36); as to claim 58, (transition zone (26) and see above rejection); as to claim 60, (fig. 1-5); as to claim 61, (figs. 4 and 5); as to claim 62, (72); as to claim 63, (fig. 5); as to claims 64 and 65, (figs. 1, 2 and 4); as to claims 66 and 67, (figs. 1-4); as to claim 68, (57 acts like a plug); as to claims 69, 70, 71, 73, and 85 (figs. 1-4); as to claim 75, (figs. 1, 3 and 5); as to claim 77, (figs. 1, 2 and 5); as to claim 78, (figs. 4 and 5); as to claims 79 and 80, (figs. 1, 2, 4 and 5); as to claim 81 (see above rejection); as to claim 83, (figs. 1-4); as to claims 86, 87, 88, 90, 91 and 92, (figs. 1, 2, 4 and 5); as to claims 93 and 94, (figs. 1-4); as to claim 96, (see above rejection).

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by Caselli U.S. Pat. No. 5,201,710.

Caselli discloses a syringe assembly having a retractable needle and a front end portion with an elongate biasing element and a one-piece needle holder extending through the biasing element, a portion of the needle holder protruding forwardly beyond all other structural elements of the assembly except the needle (figs. 1-5)

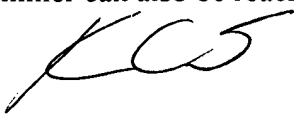
***Allowable Subject Matter***

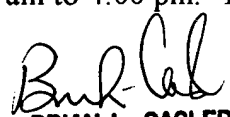
Claims 59, 72, 74 and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 82, 84 and 89 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

  
Kevin C. Sirmons  
Patent Examiner  
6/27/02

  
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